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DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

July 14, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dwight J. Zurawski
President
Tissue Medical Lasers, Inc.
4432 Anaheim Avenue NE
Albuquerque, New Mexico 87113

PURGED

Ref. # DEN-98-15

Dear Mr. Zurawski:

During an inspection of Tissue Medical Lasers, Inc., Albuquerque, New Mexico, conducted March 26, 1998 through April 24, 1998, by Investigator Cynthia Jim, it was determined that your firm manufactures a True Pulse Laser System. This product is a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that the device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to hold finished devices in quarantine or otherwise adequately control them until release for distribution by first completing all activities required in the Device Master Record (DMR) and reviewing associated data and documentation signified by an authorizing signature and date of release [21 CFR 820.80(d)]. For example, a review of [illegible] Device History Records (DHR) revealed [illegible] which lacked completion of the Performance Test Router, FRM-0028; lacked completion of the shipping checklist; failed to find laser tubes which had failed performance testing; or lacked a dated release signature.

2. Failure to document validation of processes which cannot be fully verified by subsequent inspection and test [21 CFR 820.75]. For example, the laser system displays a [illegible] or [illegible] code warning the user that calibration is required because the output is [illegible]%
greater than expected. Documentation of the validation of this process was not observed.

3. Failure to follow written complaint procedures (SOPs #[redacted]) in that the following were not used or performed: the complaint form; a unique sequential number assigned to each compliant; a complaint log; a separate file for MDR reports; performance of and maintenance of complaint investigations in the complaint file; the reporting of MDR events to FDA by telephone within five (5) calender days; written answer to every complaint; the review/closing of complaints; et al [21 CFR 820.198].

4. Failure to analyze quality records, service records, and returned product for implementing corrective and preventive action, and the failure to document the investigation and implementation of corrective actions resulting from the analysis of customer calls [21 CFR 820.100]. For example, service records, discrepant material reports (DMR), and returned material reports (RMA) have not been analyzed to determine the rate of premature failures. A trend analysis was performed on customer calls, but documentation was not generated for the review of the data and subsequent corrective actions.

5. Failure to document in the DHR the retesting and reevaluation of rework of nonconforming product, as required by 21 CFR 820.90(b)(2). For example, a laser system, [redacted] was returned, then shipped to a different customer without completing performance or alignment testing; and the voltage was changed on a laser system, [redacted], from [redacted] to [redacted] and returned to the customer without completing performance testing.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

We are in receipt of your response to the Inspectional Observations (FORM FDA 483) issued to you at the conclusion of the inspection. Your corrective actions appear to address the GMP issues and they will be evaluated during our next scheduled inspection.

Any further correspondence, if necessary, should be sent to the Food and Drug Administration, Denver District Office, to the attention of Russell W. Gripp, Compliance Officer, at the above address.

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Sincerely,

for Gary C. Dean
District Director